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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,405	09/01/2006	Zvi Sidelman	1650	3182

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EXAMINER
LIU, SAMUEL W

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
06/24/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/591,405	SIDELMAN, ZVI	
	Examiner	Art Unit	
	SAMUEL LIU	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *191,192 and 222-269* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *191-192 and 222-269* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed 10/30/07 which cancels claims 1-190 and 193-221, and adds claims 240-269 has been entered. The following Office action is applied to claims 191-192 and 222-269.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 191-192 and 222-241, drawn to a purified peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:25-4,000, and a chimeric peptide comprising the peptide (SEQ ID NOs:25-33, claims 234-239), and/or a pharmaceutical composition comprising the peptide thereof.

Group 2, claims 242-243, drawn to a method of treating an autoimmune disease comprising administering to a subject in need thereof a peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:27-4,000.

Group 3, claims 242-243, drawn to a method of treating an infectious disease comprising administering to a subject in need thereof a peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:27-4,000.

Group 4, claims 244-246, drawn to a method of treating a blood disease comprising administering to a subject in need thereof a peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:27-4,000, and/or a blood cell stimulating factor.

Group 5, claims 247-249, drawn to a method of modulating blood cell formation comprising administering to a subject in need thereof a peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:27-4,000, and/or a blood cell stimulating factor.

Group 6, claims 250-251, drawn to a method of enhancing peripheral stem cell mobilization comprising administering to a subject in need thereof a peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:27-4,000.

Group 7, claims 252-253, drawn to a method of treating a metabolic disease comprising administering to a subject in need thereof a peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:27-4,000.

Group 8, claims 254-255, drawn to a method of treating a condition associated with myeloablative doses of chemoradiotheraphy supported by autologous bone marrow or peripheral blood stem cell transplantation comprising administering to a subject in need thereof a peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:27-4,000, and/or a blood cell stimulating factor.

Group 9, claims 256-257, drawn to a method of augmenting the effect of a blood cell stimulating factor comprising administering to a subject in need thereof a peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:27-4,000, and/or a blood cell stimulating factor.

Group 10, claims 258-261, drawn to a method of enhancing colonization of donated blood stem cells in a myeloablated recipient comprising administering to a subject in need thereof a peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:27-4,000, and/or a blood cell stimulating factor.

Group 11, claims 262-263, drawn to a method of enhancing colonization of blood stem cells in a myeloablated recipient comprising administering to a subject in need thereof a peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:27-4,000, and/or a blood cell stimulating factor.

Group 12, claims 264-266, drawn to a method of treating a condition associated with a SARS infective agent comprising administering to a subject in need thereof a peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:27-4,000.

Group 13, claim 267, drawn to a method of treating a bacterial disease comprising administering to a subject in need thereof a peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:27-4,000.

Group 14, claims 268-269, drawn to a method of balancing levels of metabolites in the blood comprising administering to a subject in need thereof a peptide consisting of the amino acid sequence selected from one of SEQ ID NOs:27-4,000.

Additional Election

Regardless of the elected group, applicant is required under 35 US 121 (1) to elect a single disclosed amino acid sequence, and/or a bioactive protein (e.g., a blood cell stimulating factor), and/or a disease/condition state for the treatment to which claims are restricted.

[1] If Group 1 is elected, applicant is required to elect one amino acid sequence from claims 191-192, 222, 226-234, and 239-241 because of distinct/different amino acid sequences which determines chemical properties and biological functions of the claimed peptide.

[2] If Group 2 or 3 is elected, applicant is required to elect (i) elect one amino acid sequence from claims claim 242 because of distinct/different amino acid sequences disclosed; and (ii) one particular disease state from claim 243 because patient populations, treatment schedules and outcomes of the disease states such as "a viral disease" (genus) encompassing the diseases caused by virus such as bronchiolitis which is caused by pneumovirus) is distinct /different from AIDS.

[3] If Group 4 is elected, applicant is required to elect (i) elect one amino acid sequence from claims claim 244 because of distinct/different amino acid sequences disclosed; (ii) one particular blood disease state from claim 245 because patient populations, treatment schedules and outcomes of said disease states, such as thrombocytopenia and pancytopenia, differ from one another; and (iii) one blood cell stimulating factor from claim 246 because the amino acid sequences and biological functions of said factors such as erythropoietin and granulocyte colony stimulating factor (G-CSF) differ from one another.

[4] If Group 5 is elected, applicant is required to elect (i) elect one amino acid sequence from claims claim 247 because of distinct/different amino acid sequences disclosed; (ii) one particular type of blood cell formation because they are distinct/different in biological/ physiological mechanisms and functions as well as the outcome of said "formation", e.g., erythropoiesis versus thrombocytopoiesis; and (iii) one blood cell stimulating factor from claim 246 because the amino acid sequences and biological functions of said factors such as erythropoietin and granulocyte colony stimulating factor (G-CSF) differ from one another.

[5] If Group 6 is elected, applicant is required to elect (i) elect one amino acid sequence from claims claim 250 because of distinct/different amino acid sequences disclosed; and (ii) one blood cell stimulating factor from claim 251 because the amino acid sequences and biological functions of said factors such as erythropoietin and granulocyte colony stimulating factor (G-CSF) differ from one another.

[6] If Group 7 is elected, applicant is required to elect (i) elect one amino acid sequence from claims claim 252 because of distinct/different amino acid sequences disclosed; and (ii) one particular metabolic disease/condition from claim 253, because patient populations, treatment schedules and outcomes of said diseases/conditions, such as IDDM (type I diabetes) and hyperlididemia, differ from one another.

[7] If Group 8 is elected, applicant is required to elect (i) elect one amino acid sequence from claims claim 254 because of distinct/different amino acid sequences disclosed; and (ii) one blood cell stimulating factor from claim 255 because the amino acid sequences and biological functions of said factors such as erythropoietin and granulocyte colony stimulating factor (G-CSF) differ from one another.

[8] If Group 9 is elected, applicant is required to elect (i) elect one amino acid sequence from claims claim 256 because of distinct/different amino acid sequences disclosed; and (ii) one blood cell stimulating factor from claim 257 because the amino acid sequences and biological functions of said factors such as erythropoietin and granulocyte colony stimulating factor (G-CSF) differ from one another.

[9] If Group 10 is elected, applicant is required to elect (i) elect one amino acid sequence from claims claims 258 and 260, because of distinct/different amino acid sequences disclosed;

(ii) one blood cell stimulating factor from claims 259 and 261 because the amino acid sequences and biological functions of said factors such as erythropoietin and granulocyte colony stimulating factor (G-CSF) differ from one another.

[10] If Group 11 is elected, applicant is required to elect (i) elect one amino acid sequence from claims claim 262 because of distinct/different amino acid sequences disclosed; and (ii) one blood cell stimulating factor from claim 263 because the amino acid sequences and biological functions of said factors such as erythropoietin and granulocyte colony stimulating factor (G-CSF) differ from one another.

[11] If Group 12 is elected, applicant is required to elect one amino acid sequence from claims claim 264 because of distinct/different amino acid sequences disclosed.

[12] If Group 13 is elected, applicant is required to elect (i) elect one amino acid sequence from claims claim 267 because of distinct/different amino acid sequences disclosed.

[13] If Group 14 is elected, applicant is required to elect (i) elect one amino acid sequence from claims claim 268 because of distinct/different amino acid sequences disclosed; and (ii) one metabolite from claim 269 because the metabolites such as sugar, cholesterol, calcium, uric acid and alkaline phosphatase, are distinct in chemical structure, chemical property and biological activity.

It should be noted that this additional election of the restriction requirement is not species election but rather the additional election under 35 USC 121 since, as discussed above, the peptides are distinct/different in amino acid sequences

chemical structures, physical properties, chemical properties and/or biological functions are distinct/different from one another.

The response to the election requirement should also identify the claims readable thereon as directed to the elected invention.

Species election

This application contains claim directed to the following patentably distinct species: "protein (peptide including peptide aptamer), nucleic acid (including oligonucleic acid aptamer),

PNA (protein nucleic acid), antibody and small molecule encompassing (organic or inorganic compound)" set forth in claim 27. The species are independent or distinct because claims to the different species recite the mutually exclusive structural characteristics of such species, e.g., protein, nucleic acid an antibody. In addition, these species are not obvious variants of each other based on the current record, for example, mode of action of protein, nucleic acid and antibody, and inorganic compound (belonging to the "small molecule") are distinct from one another.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 26 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

The inventions listed as Groups 1-10 do not related to a single general invention concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The inventions listed as Groups 1-14 do not relate to a single general invention concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the claimed peptides are distinct/different in the amino acid sequences, e.g., SEQ ID NO:27 (17 amino acids) and SEQ ID NO:4,000 (26 amino acids) wherein SEQ ID NO:25 is not fragment (subsequence of SEQ ID NO:4,000) (see the above "Additional election" under USC 121). Additionally, the methods of Groups 2-15 are mutually exclusive; e.g., the method of Group 1 is drown to treating an autoimmune disease, the method of Group 3 is drawn to treating an infectious disease, whereas the method of Group 4 is drawn to treating a blood disease. The methods have different patient populations, the treatments' schedules, as well as the outcomes of the treatments thereof. Thus, the methods as claimed are not obvious variants from one another. Thus, there is no claim(s) that constitutes a special technical feature linking all claims, as defined by PCT Rule 13.2 and 37 CFR 1.475(a), as a single contribution over the art, and a holding of lack of unity is therefore proper.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Liu whose telephone number is (571)272-0949. The examiner can normally be reached on Monday-Friday, 9 am to 5:30 pro. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Manjunath N. Rao can be reached on 571-

272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel W. Liu/
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June 20, 2010